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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,503	05/16/2006	Peter Michael Waterhouse	1021565000160	9383
21839 7590 03/20/2009 BUCHANAN, INGERSOLL & ROONEY PC POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			EXAMINER ZHENG, LI	
			ART UNIT 1638	PAPER NUMBER
			NOTIFICATION DATE 03/20/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No. 10/579,503	Applicant(s) WATERHOUSE ET AL.	
	Examiner LI ZHENG	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10,11,13 and 29-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 10,11,13 and 29-31, 35,36 is/are rejected.
- 7) ☒ Claim(s) 32-34 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/25/2008</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Claims 10-11, 13, 29-36 are pending.

Election/Restrictions

2. Applicant's election with traverse of Group II, claims 10-13, including SEQ ID NO: 5, and eukaryotic translation initiation factor as species election, cancellation of claims 1-9, 12, 14-28, as well as submission of new claims 29-36 in the reply filed on 11/19/2008 are acknowledged.

Applicants contend that Tobias et al. do not describe and enable silencing of sap-sucking insect genes, nor conferring insect resistance to sap-sucking insects by providing dsRNA or siRNA having substantial sequence identity to an essential gene of a sap-sucking insect so as to have placed the public in possession of the special technical features shared by the original claims of the application (response, the paragraph bridging pages 5-6).

The office maintains that Tobias et al not only teach a method for conferring parasitic nematode and insect pest resistance to plants by expressing in a plant a dsRNA having substantial sequence identity to an endogenous gene of the nematode or insect, but also teach that said dsRNA is taken up by insects such as sap-sucking insects, by feeding via their sucking mechanism. Tobias et al further teach dsRNA comprising 25-100 base pairs, plant-expressible promoters, constitutive and specific

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promoters (e.g. phloem specific promoters) as well as essential genes (page 2, line 33- page 4, line 32; page 7, lines 17-33; page 18, lines 14-17; page 21, line 14 to page 22, line 19; Example 8; also claims 1, 6, 32 and 35). Therefore, Tobias et al. teach the technical feature linking the inventions.

Claims 10-11, 13, 29-36 including SEQ ID NO: 5 are examined on the merits.

The requirement is still deemed proper and is therefore made FINAL

Specification

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.0. See, for example, pages 15, 17, 28, 29 and 39.

Claim Objections

5. Claim 11 is objected to because the recitation "gene" is missing after the "said essential" in line 2.

6. Claims 32-34 are objected for being dependent on a rejected claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 33-34 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 recites the limitation "said essential plant sap-sucking gene" in line 1.

There is insufficient antecedent basis for this limitation in the claim.

In claim 36, the recitation "wherein said essential gene sequences have a sequence identity of higher than 95%" renders the claim indefinite. It is unclear which sequence it compares to. The metes and bounds are not clear.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

8. Claims 29-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to a method to silence a gene of a plant sap-sucking insect comprising applying to the feed of said plant sap-sucking insect dsRNA or siRNA without a transfection promoting agent wherein said dsRNA or siRNA is targeted a gene that is 70%-90% of SEQ ID NO: 5.

The specification teaches that dsRNA of SEQ ID NO: 5 and 6 encoding eIF1A of *A. gossypii* and *M. persicae*. The sequence alignment indicates that SEQ ID NO: 5 and 6 are about 92% identical (see alignment attached). However, the specification also teaches that injection of dsRNA of SEQ ID NO: 6 encoding eIF1A of *M. persicae* aphids does not resulting in higher mortality (page 33, Figure 1). Therefore, SEQ ID NO: 6 which is 92% identical to SEQ ID NO: 5 is not a target for *M. persicae* aphids.

The Applicants do not identify essential regions of the DNA of SEQ ID NO:5, nor do Applicants describe any polynucleotide sequence that has at least 70%-90% identity to SEQ ID NO:5 and being a target gene for controlling the pest, except for SEQ ID NO: 5 itself.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that

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distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of polynucleotide sequences falling within the scope of the claimed genus of polynucleotides that are 70% to 90% identical to SEQ ID NO:5 and are target gene for sap-sucking insect. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for the DNA of SEQ ID NO: 5, it remains unclear what features identify the DNA of SEQ ID NO: 5. Since said genus has not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

Scope of Enablement

9. Claim 29-31 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for targeting gene of SEQ ID NO: 5, does not reasonably provide enablement for its homology or variants as claimed. The

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specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The instant claims are drawn to a method to silence a gene of a plant sap-sucking insect comprising applying to the feed of said plant sap-sucking insect dsRNA or siRNA without a transfection promoting agent wherein said dsRNA or siRNA is targeted a gene that is 70%-90% of SEQ ID NO: 5.

The specification teaches that dsRNA of SEQ ID NO: 5 encoding eIF1A of *A. gossypii* results in higher mortality of aphids (page 35, Figure 2). However, the specification also teaches that injection of dsRNA of SEQ ID NO: 6 encoding eIF1A of *M. persicae* aphids does not resulting in higher mortality (page 33, Figure 1). The sequence alignment indicates that SEQ ID NO: 5 and 6 are about 92% identical (see alignment attached). Therefore, SEQ ID NO: 6 which is 92% identical to SEQ ID NO: 5

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is not a target for *M. persicae* aphids. Therefore undue experimentation would be required to practice invention for variants of SEQ ID NO: 5 as claimed.

Therefore, given the claim breadth, lack of further guidance and additional working example, unpredictability of the art, undue experimentation would be required for a person skilled in the art to practice the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 10-11, 13, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tobias et al (2001, WO 01/37654).

Claims 10-11, 13, 35 and 36 are drawn to a method to silence a gene of a plant sap-sucking insect comprising applying to the feed of said plant sap-sucking insect dsRNA or siRNA without a transfection promoting agent wherein said dsRNA or siRNA is targeted to an essential gene of a plant sap-sucking insect; or wherein said essential gene is a transcription factor.

Tobias et al teach a method for conferring sap-sucking insect resistance to plants by expressing in a plant a dsRNA having substantial sequence identity to an endogenous gene of the insect (claims 1 and 6). Tobias et al also teach a method for reducing expression of a sap-sucking insect mRNA comprising contacting the sap-

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sucking insect with a double stranded RNA (claims 32 and 35). Tobias et al further teach that said dsRNA is taken up by insects such as sap-sucking insects, by feeding via their sucking mechanism. Tobias et al further teach dsRNA comprising 25-100 base pairs, plant-expressible promoters, constitutive and specific promoters (e.g. phloem specific promoters) as well as essential genes (page 2, line 33- page 4, line 32; page 7, lines 17-33; page 18, lines 14-17; page 21, line 14 to page 22, line 19; Example 8; also claims 1, 6, 32 and 35). Tobias et al teach the target genes include transcription factors (page 8, line 33).

Tobias et al. does not teach applying to the feed of said plant sap-sucking insect dsRNA or siRNA without a transfection promoting agent.

Tobias et al teach dsRNA can be dissolved in water and then added to the food of the chewing pest *Manduca sexta* (page 37, Example 8).

Given the recognition of those of ordinary skill in the art of the value of control the sap-sucking insect as taught by Tobias et al., it would have been obvious for a person with ordinary skill in the art to contact the sap-sucking insect with a double stranded RNA by adding the dsRNA in the food of the sap-sucking insect. One skilled in the art would have been motivated to do so given the teaching of Tobias et al. that sap-sucking insect and chewing insect *Manduca sexta* are both piercing sucking pest (claims 4-7 and 34-35).

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed. However, claims 29-34 are free of prior art for the failure of the prior art to teach or fairly suggest a method for controlling a sap-sucking insect or reducing mRNA in a sap-sucking insect by using SEQ ID NO: 5 or its variants as the target gene.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031. The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Li Zheng/

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